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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,124	12/03/2003	Francisco Arias	2335-0108.10	4751

23980 7590 12/17/2009

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EXAMINER	
VARGOT, MATHIEU D	

ART UNIT	PAPER NUMBER
1791	

MAIL DATE	DELIVERY MODE
12/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,124	ARIAS ET AL.	
	Examiner	Art Unit	
	Mathieu D. Vargot	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-17 and 22-26* is/are pending in the application.

4a) Of the above claim(s) *26* is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 4-8* is/are allowed.

6)☒ Claim(s) *3,9,11-17 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1.Non-elected claim 26 should be cancelled to expedite prosecution.

2.Claims 1, 2 and 4-8 have been allowed, as the prior art does not teach, suggest or disclose the overall aspects of forming microneedles by coating a substrate with first and second layers of photoresist, patterning the second layer of photoresist using a photolithography technique and separating the first and second layers of photoresist from the substrate to form a microneedle structure comprised of the patterned photoresist material.

3.Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, are the first and second layer the layers that have already been set forth in amended claim 1? If so, the language in the claim needs to be amended to refer to the layers already recited.

4.Claim 3 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

5.The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 11-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al for reasons of record as set forth in paragraph 2 of the previous action. Note that while certain portions of the publication of Park et al may not

form part of the provisional, there is sufficient disclosure in paragraphs 0144-0146 and Figs. 6 and 7 to maintain the rejection. While applicant insists that Park et al does not disclose soft lithographic methods, it should be noted that the mold is made of PDMS, a soft elastomeric material that is conventionally used in "soft lithography". The mold is made from the soft elastomeric material and an organic material is subsequently molded from this soft mold. In all honesty, there appears to be very little difference between how applicant characterizes the instant soft lithography and what is disclosed in the reference. Indeed, perhaps Park et al would constitute a 102 against the broadest claims 9 and 11, with the exception that the term "soft lithography" is not explicitly disclosed. Giving applicant the benefit of the doubt, a 103 was made instead of a 102. Hence, applicant's comments directed to this aspect are believed to be misplaced.

6.Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Smith for reasons of record as set forth in paragraph 5, supra, and paragraph 3 of the previous action.

7.Claims 14 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Prausnitz et al -211 fro reasons of record as set forth in paragraph 5, supra and paragraph 4 of the previous action.

8.Applicant's arguments filed August 17, 2009 have been fully considered but they are not persuasive. Applicant's comments concerning claims 1-8 are persuasive and these claims have either been allowed (claims 1, 2 and 4-7) or would be allowed pending an obviation of the 112 issue (claim 3). However, applicant's comments with

respect to the "soft lithography" of instant claims 9, 11, 22 and 23 is simply not persuasive for reasons already noted in paragraph 5.

9.**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mathieu D. Vargot whose telephone number is 571 272-1211. The examiner can normally be reached on Mon-Fri from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on 571 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Vargot
December 14, 2009

/Mathieu D. Vargot/
Primary Examiner, Art Unit 1791